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RE: WHOLE GRAIN CITIZEN'S PETITION /2004P-0223

ConAgra Foods, Inc. ("ConAgra") is submitting this letter to comment as part of the public record on the "Whole Grain Descriptive Claims Citizen Petition" submitted on behalf of General Mills and received by FDA on May 11, 2004 (hereinafter, the "Petition"). ConAgra agrees with the Petitioner that FDA should, and has the authority to, establish content claim criteria regulations that define "good source" and "excellent source" of whole grain. However, to help promote and encourage consumers' increased intake of whole grains, ConAgra strongly supports creating content claim criteria for whole grain that is consistent with nutrient content claims already established by FDA.

ConAgra Foods, Inc. is a diversified food company with sales across a wide variety of product categories, including frozen meals, processed meats, margarine, puddings, popcorn, oils and soups. ConAgra products that comprise our 50 major brands include Healthy Choice, Orville Redenbacher's, Swiss Miss, Butterball, Banquet, Parkay, Fleischmann's, and Egg Beaters. ConAgra has approximately 40,000 employees, the vast majority of which are located in the United States, and along with our consumers, are personally affected by modifications to FDA's labeling policies.

I. BACKGROUND:

ConAgra has long understood the important role of whole grains in a nutritionally sound diet. Whole grains are significant contributors of fiber, vitamins, minerals, lignin, phytoestrogens, and phenolic compounds. Scientific studies have provided evidence that whole grain consumption is associated with a reduced risk of heart disease, diabetes and obesity when consumed as part of a low fat diet. FDA has approved health claims relating to the reduced risk of heart disease and certain cancers associated with the consumption of foods/diets that are high in whole grain content and low in fat. Major health organizations are also recommending incorporating whole grains into the diet and limiting fat; in fact, The Dietary Guidelines for Americans 2005 recommend three servings of whole grain per day with moderate fat in the diet.

ConAgra agrees with the Petition that whole grains are an important part of the diet, that consumers do not eat enough whole grains, and that more information regarding the whole content of foods must be communicated to consumers. According to consumption data, it is estimated that less than 10% of Americans consume three servings per day, and that the average consumption of whole grain is less than one serving per day. ConAgra also agrees that food companies should be incented to add more whole grains to their foods and that nutrient content claim labeling provides an excellent method to communicate nutrient benefits of food products to consumers.

However, the content claims must be meaningful, clear and useful to consumers.

II. WHOLE GRAIN CLAIM CRITERIA:

Consistent with existing FDA nutrient claim criteria, ConAgra proposes the following content claim criteria for products containing whole grain:

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Good Source of Whole Grain as 5 g of whole grain per RACC.

Excellent Source of Whole Grain as 10 g whole grain per RACC.

This proposed content claim criteria is derived from the Dietary Guidelines 2005 recommendations, which recommends the consumption of 3 servings of whole grain per day, in conjunction with the USDA defined serving of whole grain as 16 g. Multiplying 3 servings times 16grams per serving equals a daily (recommended) value of 48 g of whole grain per day. A 5 g level for a Good Source Claim is about 10% and 10 g level for an Excellent Source Claim is about 20% of this daily (recommended) value.

III. ARGUMENTS

The Petition at issue:

- A. Creates new criteria for the already existing claims "good" and "excellent" source.
- B. Creates claim criteria that would allow only a small number of products to carry a good/excellent source claim, thereby defeating the public health purpose of the rules.
- C. Is incomplete with regard to disqualification levels for whole grain claims.
- D. Contradicts already established health claim criteria and creates compliance challenges.

These actions will create unnecessary regulatory and consumer confusion, as discussed below.

- A. ***The Petition attempts to create new criteria for the already existing claims "good source" and "excellent source".***

FDA has already determined that these claims should be defined as 10% and 20% respectively, of the Daily (Recommended) Value ("DV"). A DV for whole grain can be measured by taking the amount of serving of whole grain by USDA (16 grams), and multiplying it by the new Dietary Guidelines recommendation of three servings of whole grain per day. That gives us 48grams recommended per day, or a daily value. Ten percent of 48 grams is 4.8 grams, rounded up to 5 grams for a good source claim. Twenty percent of 48 grams is 9.6 grams, rounded up to 10 grams for an excellent source.

Alternatively, the Petition's criteria are based on a serving of grain, and designates a serving an excellent source. The Petition's method:

- (1) is inconsistent with current claim criteria established by FDA;
- (2) simply takes the serving size of "grain" and calls that an "excellent source", then divides that number in half to get a good source; and
- (3) Creates a standard only very high density flour/low moisture products can achieve, like certain dry cereals or crackers.

- B. ***The Petition's claim criteria establishes an unequal playing field and will allow only a very few products to make content claim.***

The proposed 16 gram claim criteria for "excellent source" would apply to a very small number of products, whereas well-known whole grain products, such as whole grain breads and pastas, would not be considered excellent sources of whole grain. In a bread product with a standard USDA serving size of 26 grams, approximately 55% is flour, thus there are 14 grams of whole wheat. This is not enough for an excellent source claim under the Petition criteria. In fact, in the Petition (page 28), the only products to make an excellent source claim are cereals.

- C. ***The Petition is incomplete with regard to disqualification levels for whole grain claims.***

Current nutrient content claim criteria include disclosure levels of, and health claim criteria include disqualification levels of, certain nutrients of concern, such as fat, saturated fat and cholesterol. For purposes of a whole grain claim criteria, other ingredients, such as added sugars, should be reviewed as potential candidates for disqualification levels. However, these levels are eliminated by the criteria in the Petition, bringing into play the "jellybean" effect that the disclosure levels were meant to prevent. Any new claim requirements promulgated by the FDA should ensure that public health objectives, such as those outlined in the 2005 Dietary Guidelines, are furthered, not compromised.

D. The Petition would contradict already established health claim criteria and creates compliance challenges.

FDA has established criteria for whole grain health claims. Under the criteria in the Petition, to qualify for an excellent source of whole grain in bread (16 grams), the amount of flour contained in the bread would have to increase to 60%, which is HIGHER THAN THE CRITERIA FOR A WHOLE GRAIN HEALTH CLAIM. (See, Docket Nos. 99P-2209 and 03Q-0547).

Further, the Petition recommends measuring fiber in order to determine if compliance levels of whole grain are met in foods. However, refined grains and other food components, such as fruits & vegetables, are also a significant source of dietary fiber. It may be very difficult to accurately assign the fiber contribution of whole grain only.

In short, the Petition, while accurately reciting the positive benefits of whole grains, dramatically alters current FDA regulations and policy regarding content claim communications to consumers via food labels, without an identifiable public policy benefit. In fact, the Petition seeks to create a whole new category of foods for which content claims can be made, in this case whole grains. Should FDA go along with this proposal, the precedent will be set for a whole host of other "foods" that could obtain content claims, such as "good source of carrots", or "excellent source of meat." The argument would be the same as the Petition's for whole grain; i.e., that carrots have benefits beyond vitamin A, and therefore deserve their own criteria. Currently there is not even a measurement for whole grain, and instead fiber content must be used. How will that work for other foods such as carrots?

Finally, should the Petition's claim criteria be accepted, high sugar/low fiber cereals will be able to make an "excellent source of whole grain" claim, whereas products like whole wheat bread, which is already 55% whole grain, would be unable to do so. In addition, complex products like soups or meals would never be able to make a claim.

ConAgra respectfully requests that FDA deny the Petition's methodology for content claim establishment, and instead utilize already existing claim criteria for the nutrient content claims of good and excellent sources and apply them to whole grain.

Thank you.

Yours sincerely,



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